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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,040	02/04/2004	Robert F. Rioux	28-7034802001 (03-253)	3903

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EXAMINER	
WILLIAMS, KENNETH C	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,040	RIOUX ET AL.	
	Examiner	Art Unit	
	Kenneth C. Williams	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *47-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-46* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/01/04, 4/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Preliminary Amendment

1. In response to the preliminary amendment filed on February 4, 2004, claims 47-56 have been cancelled. The examiner acknowledges the formal drawings transmittal filed on January 10, 2005.

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Species I: Figure 2.

b. Species II: Figure 4

c. Species III: Figures 7 and 8

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-46 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with David T. Burse on December 2, 2005 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-46. Affirmation of this election must be made by applicant in replying to this Office action.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: electrode array, 226 (Page 16, line 21). Corrected drawing sheets in

compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Specification

7. The attempt to incorporate subject matter into this application by reference to Bingham Docket No. 2024728-7034802001 (Page 15, line 15) is ineffective because the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)).

8. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied

upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

9. The disclosure is objected to because of the following informalities:

a. Page 2, line 6, "patent" should be changed to read --patient--.

b. Page 4, lines 3 and 11, "an fluid" should be changed to read --a fluid--.

c. Page 5, line 20, "in electrode" should be changed to read --an electrode--.

d. Page 16, lines 18-21, reference characters 226 and 230 both reference electrode array.

Appropriate correction is required.

Claim Objections

10. Claims 5 and 17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 4 and 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1,11,19,26,31,35,37,41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,11,19,26,35 and 41 either reference porous or microporous structure. From the specification, no line of distinction has been made concerning the difference between porous or microporous structure. What is the difference between porous and microporous?

Claims 31,37 and 43 reference "the ablation probe is a surgical probe". From the specification, no distinction can be determined between an ablation probe and an ablation probe that is also a surgical probe. What is the difference between an ablation probe and an ablation probe that is also a surgical probe?

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 11,13-20, 22-25 and 35-46 and are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al. (U.S. Patent No. 6017338).

a. In regards to Claims 11 and 19, Brucker et al. discloses an ablation probe comprising "an elongated shaft" (See Figure 1, element 22), "an ablative element" (See Figure 1, element 30; see also column 6, lines 59-62), "a lumen" (See Figure 1, element 28; see also column 6, lines 62-65), and "a porous structure" (See Figure 1, element 26; see also column 5, lines 43-50).

b. In regards to Claims 13,17 and 22, Brucker et al. discloses an ablation probe (See Claim 11 and 19 Rejections). Brucker et al. further discloses, "the microporous structure is electrically conductive" (See column 5, lines 30-42).

c. In regards to Claims 14,20,36 and 42, Brucker et al. discloses an ablation probe (See Claims 11,19,35 and 41 Rejections). Brucker et al. further discloses, "the porous structure has interconnecting pores" (See column 5, lines 43-48).

d. In regards to Claim 15 and 23, Brucker et al. discloses an ablation probe (See Claims 11 and 19 Rejections). Brucker et al. further discloses,

"the ablative element is composed of the microporous structure" (See column 5, lines 30-53).

e. In regards to Claims 16,24,38 and 44, Brucker et al. discloses an ablation probe (See Claim 11 and 19 Rejections). Brucker et al. further discloses, "the ablative element comprises at least one electrode" (See column 4, lines 30-34).

f. In regards to Claims 18 and 25, Brucker et al. discloses an ablation probe (See Claim 11 and 19 Rejections). Brucker et al. further discloses, "a connector assembly " (See Figure 1, element 38; see also column 4, lines 46-49).

g. In regards to Claims 35 and 41, Brucker et al. discloses a tissue ablation system comprising "an ablation probe" (See Figure 1, element 20), "a perfusion lumen" (See Figure 1, element 28), "a porous structure" (See Figure 1, element 26; see also column 5, lines 30-53), "an ablation source" (See column 7, lines 63-67), and "an fluid source" (See Figure 1, element 38; see also column 4, lines 46-49).

h. In regards to Claims 37 and 43, Brucker et al. discloses a tissue ablation system (See Claim 35 and 41 Rejections). Brucker et al. further discloses, "the ablation probe is a surgical probe" (See column 3, lines 7-23). It is the examiner's position that Brucker et al. inherently discloses the limitation by the probe being capable of ablating tissue.

i. In regards to Claims 39 and 45, Brucker et al. discloses a tissue ablation system (See Claim 35 and 41 Rejections). Brucker et al. further

discloses, "the ablation source is an radio frequency (RF) ablation source" (See column 7, lines 63-67).

j. In regards to Claims 40 and 46, Brucker et al. discloses a tissue ablation system (See Claim 35 and 41 Rejections). Brucker et al. further discloses "a pump assembly" (See column 7, lines 26-34).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1,2,4-7,9,10 and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al. (U.S. Patent No. 6017338).

a. In regards to Claim 1, Brucker et al. discloses an ablation probe comprising "an elongated shaft" (See Figure 1, element 22), "an ablative element" (See Figure 1, element 30; see also column 6, lines 59-62), "a lumen" (See Figure 1, element 28; see also column 6, lines 62-65), and "a

porous structure" (See Figure 1, element 26; see also column 5, lines 43-50). Brucker et al. does not disclose "a porous structure having a porosity in the range of 20-80 percent". It is the examiner's position that there is no criticality in the range of porosity due to the wide range it encompasses. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an optimum porosity necessary for specific medical treatment.

b. In regards to Claim 2, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. does not disclose, "the porosity is in the range of 30-70 percent". It is the examiner's position that there is no criticality in the range of porosity due to the wide range it encompasses. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an optimum porosity necessary for specific medical treatment.

c. In regards to Claims 4 and 5, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. further discloses, "the porous structure is electrically conductive" (See column 5, lines 30-42).

d. In regards to Claim 6, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. further discloses, "pores with effective diameters in the range of 1-50 microns" (See column 5, lines 43-50).

e. In regards to Claims 7, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. further discloses, "the porous structure has interconnecting pores" (See column 5, lines 43-48).

f. In regards to Claims 9, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. further discloses, "the ablative element comprises at least one electrode" (See column 4, lines 30-34).

g. In regards to Claim 10, Brucker et al. discloses an ablation probe (See Claim 1 Rejection). Brucker et al. further discloses, "a connector assembly " (See Figure 1, element 38; see also column 4, lines 46-49).

h. In regards to Claim 26, Brucker et al. discloses a tissue ablation system comprising "an ablation probe" (See Figure 1, element 20), "a perfusion lumen" (See Figure 1, element 28), "a porous structure" (See Figure 1, element 26; see also column 5, lines 30-42), "an ablation source" (See column 7, lines 63-67), and "an fluid source" (See Figure 1, element 38; see also column 4, lines 46-49). Brucker et al. does not disclose "a porous structure having a porosity in the range of 20-80 percent". It is the examiner's position that there is no criticality in the range of porosity due to the wide range it encompasses. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an optimum porosity necessary for specific medical treatment.

i. In regards to Claim 27, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. does not disclose, "the porosity is in the range of 30-70 percent". It is the examiner's position that

there is no criticality in the range of porosity due to the wide range it encompasses. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an optimum porosity necessary for specific medical treatment.

j. In regards to Claim 28, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses, "the porous structure is electrically conductive" (See column 5, lines 30-42).

k. In regards to Claim 29, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses, "pores with effective diameters in the range of 1-50 microns" (See column 5, lines 43-50).

k. In regards to Claim 30, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses, "the porous structure has interconnecting pores" (See column 5, lines 43-48).

l. In regards to Claim 31, Brucker et al. discloses a tissue ablation system (See Claim Rejection). Brucker et al. further discloses, "the ablation probe is a surgical probe" (See column 3, lines 7-23). It is the examiner's position that Brucker et al. inherently discloses the limitation by the probe being capable of ablating tissue.

m. In regards to Claim 32, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses, "the ablative element comprises at least one electrode" (See column 4, lines 30-34).

n. In regards to Claim 33, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses, "the ablation source is an radio frequency (RF) ablation source" (See column 7, lines 63-67).

o. In regards to Claim 34, Brucker et al. discloses a tissue ablation system (See Claim 26 Rejection). Brucker et al. further discloses "a pump assembly" (See column 7, lines 26-34).

9. Claims 3,12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al. (U.S. Patent No. 6017338) in view of Kresch et al. (U.S. Patent No. 5456689).

In regards to Claims 3,12 and 21, Brucker et al. discloses an ablation probe (See Claim 1,11 and 19 Rejections). Brucker et al. does not disclose, "the shaft is a rigid shaft". Attention is directed to the Kresch et al. reference, which in an analogous field of endeavor discloses a rigid shaft (See Kresch et al. column 2, lines 16-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shaft of Brucker et al. with the teaching of Kresch et al. to provide a device that can be inserted percutaneously.

Allowable Subject Matter

2. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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